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Attorney Docket No.: 9233-71

In re: Soltero et al.

Serial No.: 10/036,744

Filed: December 21, 2001

For: Methods of Synthesizing Insulin Polypeptide-Oligomer Conjugates, and Proinsulin Polypeptide-Oligomer Conjugates and Methods of Synthesizing Same

Submittal of:  
Response to Restriction Requirement (3 pages)

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Attorney Docket No. 9233.71

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Soltero et al.

Confirmation No.: 3700

Application Serial No.: 10/036,744

Group Art Unit: 1646

Filed: December 21, 2001

Examiner: R. Teller

For: *Methods of synthesizing insulin polypeptide-oligomer conjugates, and proinsulin polypeptide-oligomer conjugates and methods of synthesizing same*

Date: October 23, 2003

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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**Response to Restriction Requirement**

Sir:

This is responsive to the Office Action mailed September 26, 2003 regarding the above-referenced patent application.

**Election of Claims**

In the Office Action, the pending claims 1-467 have been restricted as follows.

Group I: Claims 1-53, 248-281, 371-398 and 446-458, drawn to a method of synthesizing an insulin polypeptide-oligomer conjugate, classified in class 530, subclass 303.

Group II: Claims 54-108, 282-319 and 399-414, drawn to a method of synthesizing an insulin polypeptide-oligomer conjugate using Formula I, classified in class 530, subclass 303.

Group III: Claims 109-153 and 415-424, drawn to a method of synthesizing an insulin polypeptide-oligomer conjugate using Formula II, classified in class 530, subclass 303.

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Group IV: Claims 154-197 and 425-434, drawn to a method of synthesizing an insulin polypeptide-oligomer conjugate using Formula III, classified in class 530, subclass 303.

Group V: Claims 198-226, 320-365 and 435-445, drawn to a method of synthesizing an insulin polypeptide-oligomer conjugate using Formula IV, classified in class 530, subclass 303.

Group VI: Claims 227-247 and 366-370, drawn to a method of synthesizing an insulin polypeptide-oligomer conjugate using Formula V, classified in class 530, subclass 303.

Group VII: Claims 459-467, drawn to a method of synthesizing a C-peptide polypeptide-oligomer conjugate, classified in class 530, subclass 303.

Applicants provisionally elect Group I (claims 1-53, 248-281, 371-398 and 446-458) with traverse.

The traversal is on the basis that the claims of Group I, directed to a method of synthesizing an insulin polypeptide-oligomer conjugate, should be examined with the claims of the other groups that recite Formulas I-V or a C-peptide, respectively, as species of the invention. At a minimum, applicants request that the claims of Groups I and II be examined together, with Formula I examined as a species, and that if claims reciting this species are determined to be patentable, then the remaining claims reciting additional species be subsequently examined according to the guidelines for examination of species as set forth in MPEP § 800.

Applicants also traverse this restriction on the basis that the Examiner has not demonstrated that the requirements for claim restriction have been met. In particular, it is stated in section 803 of the MPEP that two criteria for proper restriction of claims must be met: 1) The inventions must be independent and distinct as claimed, AND 2) there must be a serious burden on the examiner if restriction is required. The MPEP further states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

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In particular, the examiner has not met the second criterion because there is no evidence provided that it would be a serious burden to examine the claims together. The MPEP states that "[f]or purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP 808.02."

Applicants believe that the Examiner has not met the requirements of a *prima facie* showing of why search and examination of all of the claims together would pose a serious burden. In particular, the claims of groups I-VII are all classified in class 530 and subclass 303 and thus the Examiner would not need to search more than a single subclass for all of these claims. Thus, applicants respectfully request that this restriction be reconsidered and withdrawn.

The Examiner is encouraged to contact the undersigned directly if such contact will expedite the examination and allowance of the pending claims.

No fee is believed due with this response. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Mary L. Miller  
Registration No. 39,303

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Cathy A. Schetzina